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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,077	11/24/2003	Anthony F. Barbet	UF-167XC3D2	8724
23557	7590	07/10/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			DUFFY, PATRICIA ANN	
		ART UNIT		PAPER NUMBER
				1645

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/722,077	BARBET ET AL.
	Examiner Patricia A. Duffy	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-6 and 8-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-6, 8-14 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date . 5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_ .

#### DETAILED ACTION

The preliminary amendment filed 4-7-04 has been entered into the record. Claims 1-6 and 8-14 are pending and subject to restriction as set forth below.

Prior to setting forth the restriction requirement, it is noted that Inventions I, II, III and IV are related as products which share an alleged common utility of protection from disease but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the polynucleotides or polypeptides lack a substantial structural feature or common core structure that are required to perform the common utility and that the products can be used in an immunoassay to determine exposure to the pathogen or make the polypeptide in vitro. Similarly, inventions V, VI, VII and VIII are methods of use that rely on products that do not share a substantial structural feature or common core structure that are required to perform the common utility.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 (in part), drawn to nucleic acids encoding the polypeptide of SEQ ID NO:26, classified in class 536, subclass 23.7.
- II. Claims 1-6 (in part), drawn to nucleic acids encoding the polypeptide of SEQ ID NO:28, classified in class 536, subclass 23.7.
- III. Claims 1-6 (in part), drawn to nucleic acids encoding the polypeptide of SEQ ID NO:30, classified in class 536, subclass 23.7.
- IV. Claims 1-6 (in part), drawn to nucleic acids encoding the polypeptide of SEQ ID NO:34, classified in class 536, subclass 23.7.

- V. Claims 8-14 (in part), drawn to methods of use of the nucleic acid of SEQ ID NO:26, classified in class 514, subclass 44.
- VI. Claims 8-14 (in part), drawn to methods of use of the nucleic acid of SEQ ID NO:28, classified in class 514, subclass 44.
- VII. Claims 8-14 (in part), drawn to methods of use of the nucleic acid of SEQ ID NO:30, classified in class 514, subclass 44.
- VIII. Claims 8-14 (in part), drawn to methods of use of the nucleic acid of SEQ ID NO:34, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV and V, VI, VII, VIII respectively are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polynucleotides can be used to make the polypeptides *in vitro* or can be used to detect the microorganism by hybridization assay *in vitro*.

Inventions I, II, III and IV are drawn to polynucleotide products. The polynucleotides are separate and distinct each from the other because they encode polypeptides that lack a common core structure and are from different microorganisms.

Inventions V, VI, VII, VIII are drawn to method of use of the polynucleotides of inventions I, II, III and IV. The methods are separate and distinct each from the other because they use polynucleotides that encode polypeptides that lack a common core structure and are from different microorganisms.

Invention I is distinct from each of inventions VI, VII and VIII and vice versa because the polynucleotides of invention I are not required to practice the methods of inventions VI, VII and VIII.

Invention II is distinct from each of inventions V, VII and VIII and vice versa because the polynucleotides of invention I are not required to practice the methods of inventions V, VII and VIII.

Invention III is distinct from each of inventions V, VI and VIII and vice versa because the polynucleotides of invention I are not required to practice the methods of inventions V, VI and VIII.

Invention IV is distinct from each of inventions V, VI and VII and vice versa because the polynucleotides of invention I are not required to practice the methods of inventions V, VI and VII.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 7:30 pm - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Patricia A. Duffy*  
Patricia A. Duffy

Primary Examiner

Art Unit 1645